February 14, 2020

Douglas Clark, Executive Director
Patented Medicines Prices Review Board
Attention: PMPRB Guideline Consultations
Box L40 Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1
Submitted via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: Proposed PMPRB Guidelines Published November 21, 2019

Dear Mr. Clark,

I am writing to provide the Canadian Generic Pharmaceutical Association's (CGPA's) feedback on the proposed PMPRB Guidelines published November 21, 2019.

The CGPA is the national association representing Canada's generic pharmaceutical industry, a group of companies which specialize in the production and marketing of high quality, affordable generic drugs. For more than 50 years, Canada's generic pharmaceutical industry has played a vital role in the country's health-care system and its economy by providing safe, effective, proven alternatives to more expensive brand-name medications. Making prescription drugs more affordable and accessible is the key value proposition of Canada's generic pharmaceutical industry.

The vast majority of generic medicines do not have patents. Some generic medicines may be patented generic drugs due to the patenting of a process or other innovation, or through a license or other arrangement with a company that has patents covering the product. Regardless of whether a generic medicine is covered by a patent or not, it must compete with other generic drugs within the market frameworks established by the provinces.

Potential Impact of PMPRB Changes on Prices of Generic Medicines

Generic medicines are used to fill more than 70 per cent of all prescriptions in Canada. Generic medicines are providing tremendous value and savings for Canadians, largely due to the work the CGPA has done with the pan-Canadian Pharmaceutical Alliance (pCPA).

The pCPA and CGPA have had a 5-year generic drug pricing agreement ("5-Year Agreement") in place since April 1, 2018. This follows an earlier agreement, which resulted in substantial savings for Canadians.

The 5-Year Agreement includes a tiered pricing model which has different pricing levels depending on the number of competitors in the market. These prices are fully transparent and apply to payers in both public and private markets. Prices of generic drugs are calculated and set by the pCPA as a percentage of the price of the reference originator product at the time the first version of that generic medicine seeks to be listed on provincial formularies. Any subsequent change in the price of the originator product does not affect the price of a generic medicine already listed on provincial formularies. However, generic drug manufacturers begin development of new medicines several years prior to their launch on the market. Changes in reference brand products currently on the market (for example as a result of the new international country price comparison tests) would affect the pricing of the generic products under development.

Because of this reference-based pricing system for generic medicines in Canada, the CGPA has been concerned about the changes to the *Patented Medicines Regulations* and PMPRB framework for several years. Generic pricing levels in Canada are internationally competitive, and any reduction in originator prices must not have a corresponding impact generic drug prices.

The 5-Year Agreement includes a review clause that requires the pCPA and CGPA to review the changes to the PMPRB framework and address potential impacts on generic drug prices. This clause was included to maintain the integrity of the agreement, ensure generic drug prices remain at sustainable levels, and lower the potential risk of drug shortages for Canadians.

However, the full impact of the changes on originator prices remains unclear and the topic of much debate, creating uncertainty about the impact of the changes on the 5-Year Agreement. The estimates of the impact of the *Patented Medicines Regulations* and PMPRB framework changes vary greatly. While the RIAS to the Regulations published August 21, 2019 estimates that originator revenues will be reduced by 10.8 per cent by year 10, industry estimates suggest that the impact on originator prices will be substantially higher.

The importance of the 5-Year Agreement and the internationally competitive prices of generic medicines in Canada are recognized by the PMPRB in various reports. This includes the PMPRB's *Generics 360, 2018* report, which notes:

> Over the past decade, generic price-setting policies initiated by individual provincial governments and through the pan-Canadian Pharmaceutical Alliance (pCPA) have resulted in a notable decline in generic prices. The latest initiative, a five-year joint agreement between the pCPA and the Canadian Generic Pharmaceutical Association (CGPA), has gained the greatest ground, bringing Canadian prices closely in line with international norms.

PMPRB data shows that Canadian prices for generic prescription medicines dropped to five percent below average or mean prices in comparator countries in 2018. The PMPRB's data also shows that, since 2007, the average price of generic prescription medicines in Canada has fallen by nearly 60 per cent, with prices of some of the top-selling generics dropping by an average of 80 per cent. While prices of generic medicines have fallen in markets around the world, Canada has experienced the steepest decline of all OECD countries.

In announcing the pCPA-CGPA 5-Year Agreement, the parties issued a joint statement which noted the following[1]:

[1] https://www.newswire.ca/news-releases/a-joint-statement-from-the-pan-canadian-pharmaceutical-alliance-and-the-canadian-generic-pharmaceutical-association-671651014.html

- As of April 1, 2018, the prices of nearly 70 of the most commonly prescribed drugs in Canada will be reduced by 25%-40%, resulting in overall discounts of up to 90% off the price of their brand-name equivalents. These drugs include those used to treat high blood pressure, high cholesterol, and depression, and are collectively used by millions of Canadians.

- More than 70% of all prescriptions reimbursed under Canada's public drug plans are generic drugs. This new initiative will not only provide savings to patients and increase the sustainability of drug plans, but will also improve pricing consistency across the country, and help drug plans increase access to new drugs in Canada.

- Previous joint efforts between pCPA and CGPA have resulted in savings of over $1 billion to participating drug plans over the past five years, and will continue to save $250 million per year. This initiative builds upon that foundation, and is estimated to save an additional $385 million in the first year, and up to $3 billion over the next five years through a combination of price reductions and the launch of new generic drugs. Savings to patients and employers are expected to match or exceed those achieved by Canadian governments.

- A key component of this initiative is that tendering will not be pursued by the participating drug plans over the five-year term. The generic drugs covered in this initiative are manufactured by multiple generic companies, helping to ensure a stable supply for Canadian patients. Pricing stability and predictability will also help to ensure that generic pharmaceutical manufacturers can continue to invest in bringing new cost-saving generic drugs to the Canadian market in the coming years.

Recommendation:
In light of the uncertainty with respect to originator prices, the CGPA urges the PMPRB to consult closely with both the pCPA and the CGPA as it finalizes its Guidelines and to continue that close consultation in the future to prevent serious negative impacts on the integrity of the 5-Year Agreement as well as on the introduction and sustainability of generic medicines in Canada.

Complaints-Based Reporting for Patented Generic Medicines

One of the five goals of the final *Patented Medicine Regulations* published in Canada Gazette Part II on August 21, 2019, as set out in the associated Regulatory Impact Assessment Statement, is to reduce PMPRB reporting obligations for patented veterinary, over-the-counter, and generic medicines. With respect to patented generic medicines it states:

> The Amendments also extend the same reduced reporting obligations to patented generic medicines (i.e. medicines approved by means of an abbreviated new drug submission, or ANDS, but that are subject to patent protection). Patentees of generic medicines typically face greater competition, and the risk of excessive pricing due to market power is generally not cause for concern. These Amendments will spare patentees unnecessary reporting burden for medicines that pose a lower risk of excessive pricing. It will also allow the PMPRB to focus its resources on medicines that pose a more substantive risk of excessive pricing.

From the CGPA's perspective, the above passage accurately recognizes that patented generic drugs:

- typically face greater competition than other drug product categories, and therefore have a reduced risk of excessive pricing due to market power;
- should be spared unnecessary reporting obligations, since they pose a lower risk of excessive pricing; and
- pose a lower risk of excessive pricing, and that reduced reporting for this product category would enable the PMPRB to conserve resources and focus on medicines that are at a higher risk of excessive pricing.

The CGPA appreciates and supports this reduced reporting obligation in respect of patented generic drugs, as well as the reasons underpinning this proposed approach for the PMPRB. However, the CGPA was disappointed that the definition of *generic medicine* in the final *Regulations* was based on Health Canada approval pathways instead of something more reflective of the market-based realities for these products.

Health Canada officials have acknowledged to CGPA that a generic medicine was defined in the *Regulations* as a product that is approved through the ANDS pathway because they had difficulty creating a more accurate legal definition that was inclusive of all generic medicines.

Since the July 1, 2016 reporting period the PMPRB has had a complaints-based reporting system in place for **all** patented generic medicines, regardless of Health Canada pathway through which the generic medicine is approved. This policy was added to the PMPRB's Compendium of Policies, Guidelines and Procedures in February 2017, and is supported by the CGPA.

Recommendation:
All generic medicines pose a low risk of excessive pricing, regardless of which approval pathway they are reviewed under by Health Canada. As such, the Board would be justified in extending the complaints-based reporting system that is proposed for patented generics that are approved through the ANDS pathway to include all generic medicines. This approach is fully consistent with the Board's existing complaints-based reporting policy for all generic medicines. There are also no legal reasons that would prevent the Board from adopting this approach in the Guidelines.

Thank-you for reviewing these submissions of the Canadian Generic Pharmaceutical Association. We look forward to discussing these concerns with you in greater details.

Sincerely,

Jim Keon
President
Canadian Generic Pharmaceutical Association